DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 11 1996

WARNING LETTER

Mr. Brian Perkins
President
McNeil Consumer Products Co.
7050 Camp Hill Road
Fort Washington, Pennsylvania 19034-2299

Ref: 97-HFD-312-06

Dear Mr. Perkins :

This letter concerns the recent dissemination of certain trade promotional materials (described below) for "Nicotrol," marketed by your firm for over-the-counter (OTC) drug use under a new drug application (i.e., NDA 20-536) approved by the Food and Drug Administration (FDA) on July 3, 1996. These materials constitute "labeling" under the Federal Food, Drug, and Cosmetic Act (FFDCA) [see §201(m)(2)], and are not a part of the NDA-approved labeling. Because of their misleading nature, certain statements included in this labeling, such as those identified below, cause "Nicotrol" to be misbranded [§502(a) of the FFDCA].

Trade promotional labeling entitled, "NEW Nicotrol...," which includes the statement,

"...Weaning provides no advantage to quit rates.

Review of two separate non-comparative studies presented at the nonprescription drugs advisory committee on April 19, 1996 showed patches with weaning regimens and patches without have similar quit rates..."

also includes specific quit-rate comparisons between "Nicotrol" and "NicoDerm CQ" in the form of two bar graphs comparing 6-week and 6-month quit rates for "Nicotrol" to 10-week and 6-month quit rates for "NicoDerm."

In addition, a brochure entitled, "QUESTIONS & ANSWERS...OTC Nicotrol...," includes the following text:

"...How is Nicotrol different from other nicotine patches?

No studies have done a side by side comparison of patches but a meta-analysis has shown that all patches are equally effective...."

> **"...Will I experience morning cravings with Nicotrol?**
>
> **...clinical studies have shown no benefit in using a 24-hour patch over a 16-hour patch. The quit rates for both formats are comparable...."**

Absent substantiation through controlled head-to-head clinical trials, comparative efficacy claims such as these are misleading. This position was previously conveyed by this Agency [i.e., the Division of Anesthetic, Critical Care, and Addiction Drug Products (HFD-170)] to your firm on November 1, 1995.

The above referenced "QUESTIONS & ANSWERS..." brochure also includes the following text:

> **"...Who should use the Nicotrol patch?**
>
> **All smokers who are serious about quitting can benefit from Nicotrol...."**

Since "Nicotrol" has not been approved by FDA for OTC use by "All" smokers (e.g., light smokers or those smoking $\leq$ 10 cigarettes per day, or by smokers under 18 years of age), representations that "All" smokers can benefit from "Nicotrol" are misleading.

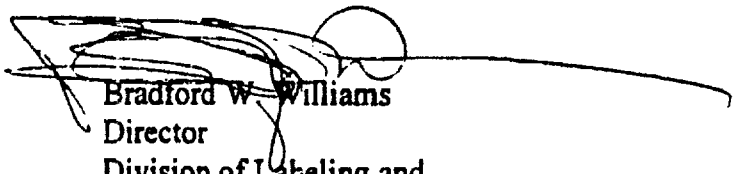
Therefore, as cited above, "Nicotrol" is misbranded under the FFDCA [§502(a)].

In addition, we note that the marketing of "Nicotrol" with "labeling" that is not the subject of an FDA-approved NDA causes such article to be an unapproved "new drug" [§505(a) of the FFDCA].

This letter is not intended to be a comprehensive review of the above named product or other products marketed by your firm. It is your responsibility to assure that all requirements of the FFDCA and the regulations promulgated thereunder are being met. Federal agencies are routinely advised of the issuance of Warning Letters so that they may take this information into account when considering the award of contracts. You should take prompt action to correct these violations.

We request that you reply within fifteen (15) days of your receipt of this letter stating the action you will take to correct the violations described above. Failure to promptly correct these violations may result in enforcement action being initiated without further notice. The FFDCA provides for seizure of illegal products (§304) and for injunction (§302) against the manufacturer and/or distributor of illegal products.

Sincerely yours,



Bradford W. Williams
Director
Division of Labeling and
Nonprescription Drug Compliance (HFD-310)
Office of Compliance
Center for Drug Evaluation and Research